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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,923	09/09/2003	Frank C. Kohn	17396/09156	2292
27530	7590	07/12/2006	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP 1320 MAIN STREET, 17TH FLOOR COLUMBIA, SC 29201			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 07/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,923

Applicant(s)

KOHN, FRANK C.

Examiner

Alton N. Pryor

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,13,14,17 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,6-12,15,16,18-20 and 22-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/7/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 recite the limitation "the insect" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,6-12,15,16,18-20,22-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is to a method of treating a seed of a particular type with a composition comprising pyrethrin or synthetic pyrethroid to prevent damage by pests to shoots and foliage of the plant developing from the seed. The composition can optionally comprise an additional pesticide

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibited the desired pesticidal activities (i.e. which additional pesticides when combined with a pyrethrin or synthetic pyrethroid, then applied to seed types claimed would be effective in protecting said plant parts from being damaged by pests). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any pesticidal regimen on its face. The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, their mode of action is often unknown or very unpredictable and administration of the additional pesticide can be accompanied by undesirable side effects such as stunting plant growth which could eventually lead to plant death.

Thus, in the absence of a showing of correlation between all the additional pesticide combined with the synthetic pyrethroid and protection of said plant parts after instant seed treatment claimed, one of ordinary skill in the art is unable to fully predict possible results from the administration of the additional pesticide due to the unpredictability of the role of the huge number of additional pesticide set forth in the claims.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to identify each class of pesticides other than pyrethrins and synthetic pyrethroids, and then determine which said classes of pesticides when combined with a pyrethrin or synthetic pyrethroid would be effective in protecting said plant parts from damage by pests.

5) Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is found on pages 60-62 wherein *in vitro* chromogenic assay was used to identify and evaluate inhibitions of recombinant human secreted phospholipase A₂ is provided. However, that embraces a myriad of

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conditions. In addition, the gap between *in vitro* activity and *in vivo* utility is large enough to warrant thorough and compelling *in vivo* or clinical data.

6) Existence of working examples.

No working examples are provided for the composition comprising additional pesticides. Note in Applicant's response filed 4/26/06, Applicant admits that specification does not identify any additional pesticide.

7) Breadth of claims.

Claims are extremely broad due to the vast number of possible additional pesticides encompassed by the instant invention.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the unpredictability in the pesticidal art, it is noted that each embodiment of the invention is required to be individually assessed for pesticidal activity by *in vitro* and *in vivo* screening to determine which additional pesticides exhibit the desired pesticidal activity.

Hence, the specification fails to provide sufficient support of the use of the additional pesticides of the claims for the protecting plants from damage by pests. As a result necessitating one of ordinary skill in the art to perform an exhaustive search to determine which classes of additional pesticides can be combined with pyrethrins or synthetic pyrethroids to protect said plant parts from being damaged by pests in order to practice the claimed invention.

Genentec Inc. V. Novo Nordisk A/S (CAFC) 42 USPQ 2D 1001, states that:

"a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test all classes of additional pesticides to determine which classes would be effective in meeting the scope of the claims, with no assurance of success.

Lastly, with regards to the prevention of claimed plant damages), the specification lacks the critical steps necessary in presenting some type of predictable response in a population of hosts (plants) deemed necessary to prevent the diseases. Reasonable guidance with respect to preventing the plant damages rely on quantitative analysis from defined plant populations which have been successfully pre-screened and are predisposed to particular types of damages. This type of data might be derived from widespread plant damage analysis. The essential element towards the validation of a preventive regimen is the ability to test the pesticide on plants monitored in advance of damages and link those results with subsequent histological confirmation of the presence or absence of damages. This irrefutable link between antecedent pesticide (compound) and subsequent knowledge of the prevention of the damages is the essence of a valid preventive agent. Further, a preventive administration also must assume that the regimen will be safe, tolerable, and healthy for the plant susceptible to the damage. All of this underscores the criticality of providing workable examples which is not disclosed in the specification, particularly in an unpredictable art such as plant therapy.

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In view of the teachings above, and the lack of guidance and or exemplification in the specification, it would not be predictable that the invention of preventing plant damages would function as contemplated. Thus, it would require undue experimentation by one of skill in the art.

Claims 1-3,6-12,15,16,18-20,22-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. The specification lists in paragraph 24 several suitable pesticides. However, the specification does not inform an artisan that these are the additional pesticides. The term "additional pesticides" occurs in the claims, but no additional pesticides are actually listed.

Claims employing additional pesticides are neither described nor exemplified and the specification does not inform the public of the limits of the monopoly asserted.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. There is no additional pesticide named or identified.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,6,25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatehouse et al (Pesticide Science, 1982, vol. 13 no. 2, 109-18). Gatehouse teaches a method of applying permethrin to seed of winter wheat crops to protect wheat from becoming damaged by wheat bulb fly larvae (pests). Method results in the seed being treated with permethrin, which is also protected from becoming damaged by said pests. See abstract. Permethrin is a synthetic pyrethroid, which has a vapor pressure that is lower than that of tefluthrin. See instant claim 2. The reference does not teach the control of cutworm damage. The reference abstract is silent to rate of application rate of permethrin to seed (application rate equal to or greater than 88g of permethrin per 100 kg seed). Note both instant invention and prior art discloses the same active step, i.e., application of permethrin to seed. It is obvious that the same benefit acquired in Applicant's (control of cutworms) would have been effective in Gatehouse's invention. One would have expected this since both inventions teach the application of permethrin to wheat seeds. It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat) growth. It is

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possible that artisan would have discovered that instant application rate is most effective. Where the provide teaches all claim limitations with the exception of a defined application rate as instantly claimed applicant must present a showing of the criticality of the application rate claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,6-12,15,16,18-20,22-35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3,26,28,29,31-35,41-48 of U.S. Patent No. 6660690. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and patent disclose similar inventions. USPN '690 teaches the application of a composition comprising permethrin and an additional insecticide to seeds (corn, soybean, cotton)

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with and without a transgenic event (heterologous gene derived from *Bacillus*, *Rhizobium*, *Serratia*) in order to protect developing plants from damage by pests such as larval from Lepidopteran sp. Insect, cutworms and corn borers. Seeds having transgenic event encodes for the expression of protein that is active against a first pest, with the composition comprising at least permethrin having activity against a second pest. Claims 10-12, 15, and 16 describe chemical and physical properties that are inherent to permethrin. The instant claims are silent to rate of application rate of permethrin to seed (application rate equal to or greater than 88g of permethrin per 100 kg seed). It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat, corn, cotton) growth. It is possible that artisan would have discovered that instant application rate is most effective. Where the prior art teaches all claim limitations with the exception of a defined application rate as instantly claimed applicant must present a showing of the criticality of the application rate claimed.

Claims 1,9-12,15,16,18,19,24 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,7,14-16,18-21,24-29,31 of U.S. Patent No. 6713077. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and patent disclose similar inventions. USPN '077 teaches the application of a composition comprising permethrin and an additional insecticide to seeds (corn,

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soybean, cotton) in order to protect developing plants from damage by pests. Claims 10-12, 15, and 16 describe chemical and physical properties that are inherent to permethrin. The instant claims are silent to rate of application rate of permethrin to seed (application rate equal to or greater than 88g of permethrin per 100 kg seed). It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat, corn, cotton) growth. It is possible that artisan would have discovered that instant application rate is most effective. Where the prior art teaches all claim limitations with the exception of a defined application rate as instantly claimed applicant must present a showing of the criticality of the application rate claimed.

Claims 1-3,6-8,37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3,8-10 of U.S. Patent No. 6903093. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and patent disclose similar inventions. USPN '093 teaches the application of a composition comprising synthetic pyrethroid (See USPN '093 column 6 lines 5-13 where permethrin is listed as a synthetic pyrethroid) and an additional insecticide to seeds (See USPN '093 column 9 lines 28-40 where seeds listed are of corn, soybean, and cotton) in order to protect developing plants from damage by pests. The instant claims disclose application rate of greater than 200 gm pyrethroid (permethrin) per 100 kg seed. The instant invention

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claims an application rate equal to or greater than 88g of permethrin per 100 kg seed which encompasses the application rate claimed in USPN '093. It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat, corn, cotton) growth. Where the prior art teaches an application rate that is encompassed by the instant claims, applicant must present a showing of the criticality of the application rate claimed.

Claims 1-3,6-12,15,16,18-20,22,23,25-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-13,15-23 of copending Application No. 11072215. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and patent disclose similar inventions. USPA '215 teaches the application of a composition comprising synthetic pyrethroid (See USPA '215 where permethrin is listed as a synthetic pyrethroid) and an additional insecticide to seeds (corn, soybean, cotton) with and without a transgenic event (heterologous gene derived from *Bacillus*, *Rhizobium*, *Serratia*) in order to protect developing plants from damage by pests such as larval from *Lepidopteran* sp. Insect, cutworms and corn borers. Seeds having transgenic event encodes for the expression of protein that is active against a first pest, with the composition comprising at least permethrin having activity against a second pest. Claims 10-12, 15, and 16 describe chemical and physical properties which are inherent to permethrin. The instant claims disclose application rate of greater than

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200 gm pyrethroid (permethrin) per 100 kg seed. The instant invention claims an application rate equal to or greater than 88g of permethrin per 100 kg seed which encompasses the application rate claimed in USPN '093. It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat) growth. Where the prior art teaches an application rate that is encompassed by the instant claims, applicant must present a showing of the criticality of the application rate claimed.

Claims 1-3,6-12,15,16,18-20,22,23,25-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,9-25 of copending Application No. 11028782. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and patent disclose similar inventions. USPA '782 teaches the application of a composition comprising synthetic pyrethroid (See USPA '782 page 9 second full paragraph where permethrin is listed as a synthetic pyrethroid) and an additional insecticide to seeds (corn, soybean, cotton) with and without a transgenic event (heterologous gene derived from Bacillus, Rhizobium, Serratia) in order to protect developing plants from damage by pests such as larval from Lepidopteran sp. Insect, cutworms and corn borers. Seeds having transgenic event encodes for the expression of protein that is active against a first pest, with the composition comprising at least permethrin having activity against a second pest. Claims 10-12, 15, and 16 describe

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chemical and physical properties which are inherent to permethrin. The instant claims are silent to rate of application rate of permethrin to seed (application rate equal to or greater than 88g of permethrin per 100 kg seed). It is obvious that one having ordinary skill in the art would have been expected to determine optimum application rate of permethrin to seed. One would have been motivated to do this in order to determine what application rate is effective at controlling pests while at the same time promoting healthy plant (wheat, corn, cotton) growth. It is possible that artisan would have discovered that instant application rate is most effective. Where the prior art teaches all claim limitations with the exception of a defined application rate as instantly claimed applicant must present a showing of the criticality of the application rate claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Election Status

The elected invention comprising permethrin is not allowable. See rejections above.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Alton N. Pryor', is written above the printed name.

Alton Pryor
Primary Examiner
AU 1616